Remarks

Amendment to claims

Claims 16, 19 and 20 are amended to depend on claim 1. Claims 28 and 29 are amended to provide the antecedent basis for the crosslinking agent or initiator recited therein. Support is found at p. 22, lines 21-31.

Rejections under 35 U.S.C. § 112, 2nd paragraph

Claims 16, 19, 20, 28 and 29 were rejected as indefinite under 35 U.S.C. § 112, second paragraph. Claims 16, 19 and 20 are amended to depend on claim 1, which was previously amended to incorporate the limitations of claims 2, 9 and 10. Claims 28 and 29 are amended to provide the antecedent basis for the crosslinking agent or initiator recited therein.

Double patenting rejection

Claims 1, 6, 11, 12, 25, 27-31 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 2-7 of U.S. Patent No. 6,241,771, which issued over U.S. application Serial No. 09/131,716. The applicants disagree that claims 1, 6, 11, 12, 25, 27-31 are obvious over claims 2-7 of U.S. Patent No. 6,241,771. However, since the present application is a continuation of U.S. application Serial No. 09/131,716, the applicants submit a terminal disclaimer to disclaim any additional patent term of the present application over the patent term of U.S. Patent No. 6,241,771.

Rejections under 35 U.S.C. 102

Claims 1, 6, 11, 12, 25 and 33 were rejected as anticipated under 35 U.S.C. 102(e) by U.S. Patent No. 5,741,329 to Agrawal et al. ("Agrawal"). The applicants respectfully traverse this rejection.

The claimed invention

Claims 1, 6, 11, 12, 25 and 33, and other claims of the present application are drawn to an interbody spinal fusion device. The device comprises (1) 25-100% polymer producing acidic products or low molecular weight resorbable fragments upon hydrolytic degradation, (2) one or more void spaces, and a (3) pH buffering agent or neutralizing agent. The polymer is a resorbable polymer such as polydioxanone, poly(epsilon-caprolactone), polyanhydride, polyester, copoly(ether-ester), polyamide, polylactone, poly(propylene fumarate), and poly(lactide-co-glycolide) with a lactide to glycolide ratio in the range of 0:100% to 100:0% inclusive, and can be crosslinked to form an interpenetrating network. The void spaces may contain a grafting material for facilitating bony development and/or spinal fusion. The pH buffering agent or neutralizing agent can be, for example, hydroxyapatite, carbonates, phosphates, acetates, succinates and citrates.

Agrawal

Agrawal describes a pH-controlling device formed of a biodegradable polymer and a pH-controlling substance or buffering agent (col. 2, lines 6-42). The biodegradable polymer can be polyglycolic acid, polylactic acid, and poly(glycolic acid-co-lactic acid) (col. 3, lines 50-59). The pH buffering agent or pH-controlling agent can be calcium carbonate, sodium bicarbonate, calcium hydroxyapatite, or a mixture thereof (col. 4, lines 23-26) in the amount of about 1% to 99% by weight or 5% to 30% by volume of the polymer (col. 4, lines 31-33). Agrawal does not teach or suggest an interbody spinal fusion device formed of the materials described therein. Nor does Agrawal teach or suggest a device having one or more voids. Therefore, Agrawal does not anticipate claims 1, 6, 11, 12, 25 and 33 under 35 U.S.C. 102(e).

Rejections under 35 U.S.C. 103

Claims 1, 3, 4, 6, 11, 12, 17, 18, 25, 26, 28, 29, 30 and 33 were rejected under 35 U.S.C. 103(a) as obvious over U.S. Patent 4,961,740 to Ray, et al. ("Ray") in view of Agrawal. Claim 4 was further rejected as obvious under 35 U.S.C. 103(a) over Ray in view of U.S. Patent No. 5,192,327 to Brantigan ("Brantigan"). Claims 17 and 18 were further rejected under 35 U.S.C. 103(a) as obvious over Ray in view of U.S. patent No. 4,655,777 to Dunn et al. ("Dunn"). Claims 26, 28 and 29 were further rejected as obvious under 35 U.S.C. 103(a) as obvious over Ray in view of U.S. Patent No. 5,527,864 to Suggs et al. ("Suggs"). The applicants respectfully traverse these rejections if they are applied to the claims as amended.

Ray

Ray describes an interbody fusion cage formed of stainless steel, titanium, ceramics, or a **super-strength** polymer or composites such as super-high-density polyethylene, glass, or graphite (col. 4, lines 31-35). The polymer can be biodegradable (col. 4, line 39). The fusion cage has a threaded outer surface and an internal cavity which is adapted to be filled with bone chips (col. 3, lines 39-41). Ray does not teach that using up to 75% a pH-neutralizing agent or buffering agent to form the interbody fusion cage, though it states that hydroxyapatite can be used as a bone activating matter placed in the cavity of the cage (col. 4, lines 46-48).

Ray and Agrawal is not combinable. In Agrawal, the device is not required to be made of a super-strength material. As described at col. 4, lines 1-34, the device described in Agrawal is formed of a polymer in combination with sodium biocarbonate as an alkaline agent of choice in a amount of 1% to 99% by weight or 5% to 50% by volume of the polymer used. One of ordinary skill in the art would recognize, sodium bicarbonate is highly water soluble and has no

mechanical strength when placed in water. A polymer with 99% sodium bicarbonate placed therein would not be a super-strength polymer as required by Ray (see, Ray, col. 4, line 32). Even if only 1% sodium bicarbonate is included in the polymer, the polymer composition may not qualify as a super-strength polymer because the sodium bicarbonate, when leached out, would render the polymer body highly porous. A porous polymer would not have a super-strength as required by Ray. As such, described subject matter in Ray and that in Agrawal are mutually exclusive. Ray and Agrawal are therefore not combinable.

Even if one argued that Ray and Agrawal were combinable, one of ordinary skill in the art still would not have a reasonable expectation of success of the claimed interbody spinal fusion device. As discussed above, Ray teaches that the material forming the device therein must have a super-strength. The above discussion shows that a material formed of a polymer and a substantial amount of a pH buffering or neutralizing agent such as sodium bicarbonate may not qualify as having a super-strength. The claimed interbody spinal fusion device may comprise up to 75% a pH buffering agent or pH neutralizing agent. Therefore, one of ordinary skill in the art taught by Ray and Agrawal might consider the material used in the present application as having a super-strength so as to have a reasonable expectation of success of the claimed interbody spinal fusion device. Therefore, Ray in view of Agrawal would not render claims 1, 3, 4, 6, 11, 12, 17, 18, 25, 26, 28, 29, 30 and 33 *prima facie* obvious under 35 U.S.C. 103.

Claim 4 was further rejected as obvious under 35 U.S.C. 103 over Ray in view of Brantigan. The applicants respectfully disagree.

Brantigan teaches a prosthetic device to integrate with an support vertebrae in a vertebral column (col. 1, line 64 to col. 2, line 43). The prosthetic device has to be biologically acceptable but inert (col. 1, lines 64-65). Brantigan does not define the term "inert". However, one of ordinary skill in the art would recognize that the term "inert" refers to being chemically stable, e.g., the device would not degrade under physiological conditions when used in a human body. This notion is confirmed by the description at col. 2, lines 52-55 which states that the device provides "a permanent mechanically secure repair with living tissue." In contrast, the claimed device is formed of a polymer which degrades into acidic fragments upon hydrolysis. Therefore, Brantigan is irrelevant to the claimed device. Moreover, to the extent that Ray is relevant, Ray teaches that the material forming the device described therein can be a biodegradable polymer having a super-strength. Ray and Brantigan are thus not combinable.

Even if Brantigan were relevant and combinable with Ray, Ray and Brantigan combined would not disclose the claimed device. None of Ray and Brantigan teach a pH buffering or neutralizing agent as required in the claimed device. None of Ray and Brantigan provide the motivation for one of ordinary skill in the art to make the claimed device having up to 75% a pH buffering or neutralizing agent. Moreover, as the foregoing discussion shows, Ray requires the material used therein to have a super-strength, and Brantigan requires teaches that the device described therein is "inert." Therefore, even if Ray and Brantigan provided the motivation for including up to 75% a pH buffering or neutralizing agent in the device, one of ordinary skill in the art still would not have a reasonable expectation of success of the claimed device which degrades and has up to 75% a pH buffering or neutralizing agent which may render the material

not qualified as having a super-strength. Accordingly, Ray in view of Brantigan would not render claim 4 *prima facie* obvious under 35 U.S.C. 103.

Claims 17 and 18 were further rejected under 35 U.S.C. 103 as obvious over Ray in view of Dunn. The applicants respectfully disagree.

Dunn teaches a method of producing biodegradable prostheses and using the prostheses in medical applications (col. 3, lines 16-22). The prostheses were formed of calcium aluminate (CaAl), β-Whitelockite (β-TCP) (col. 3, lines 20-22; col. 3, line 26 to col. 4, line 24) or CMC fibers (col. 8, line 55 to col. 9, line 32) and as reinforcing fibers (col. 10, line 55 to col. 11, line 23) and a biodegradable polymer (col. 11, line 24 to col. 12, line 31). Dunn does not teach or suggest making an interbody spinal fusion device. Nor does Dunn describe or teach a pH buffering or neutralizing agent.

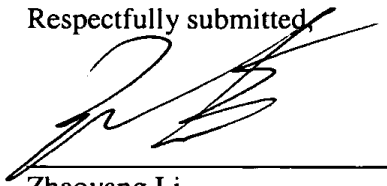
Ray in combination of Dunn, therefore, fail to teach a pH buffering or neutralizing agent as required in claims 17 and 18. Nor do Ray and Dunn provide the motivation for one of ordinary skill in the art to make and use an interbody spinal fusion device comprising up to 75% a pH buffering or neutralizing agent. Further, Ray requires the material forming the device described therein to have a super-strength. As the discussion of Ray in view of Agrawal shows, one of ordinary skill in the art may not expect a material comprising a polymer and up to 75% a pH buffering or neutralizing agent could be qualified as having a super-strength as required in Ray. Therefore, one of ordinary skill in the art, taught by Ray and Dunn, would not have a reasonable expectation of success of the claimed device. Accordingly, Ray and Dunn combined would not render claims 17 and 18 *prima facie* obvious under 35 U.S.C. 103.

Claims 26, 28 and 29 were further rejected as obvious under 35 U.S.C. 103 over Ray in view of Suggs. The applicants respectfully disagree. Suggs teaches the preparation of poly(propylene fumarate-co-ethylene oxide) (col. 2, lines 25-50). Suggs does not teach the formation of an interbody spinal fusion device comprising a bioresorbable polymer and a pH buffering or neutralizing agent.

Ray and Suggs in combination fail to teach an interbody spinal fusion device comprising a polymer and up to 75% a pH buffering or neutralizing agent. Nor Ray and Suggs provide the motivation for one of ordinary skill in the art to make and use an interbody spinal fusion device having up to 75% a pH buffering or neutralizing agent. Besides, Ray requires the material forming the device described therein to have a super-strength. As the discussion of Ray shows (*supra*), one of ordinary skill in the art therefore would not have a reasonable expectation of success of the claimed device which may contain up to 75% a pH buffering agent or neutralizing device. Therefore, Ray and Suggs, combined would not render claims 26, 28 and 29 *prima facie* obvious under 35 U.S.C. 103.

Allowance of claims 1, 3-8, 11-20, 24-31 and 33 is honestly solicited.

Respectfully submitted,



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